

REMARKS

The Examiner has rejected claim 1 under 35 U.S.C. § 103(a) as being unpatentable over Adair U.S. Patent No. 5,311,858 in view of Wilk U.S. Patent No. 5,232,440. Claim 7 is allowable.

Applicant respectfully traverses the rejection of claim 1 over Adair in view of Wilk. Claim 1 recites a "monolithic memory metal tube of single-piece construction programmed for an effect selected from the group of effects consisting of memory effect and superelasticity" and further recites that the "slotted retrieval basket section is capable of expansion and contraction to surrounding contact, capture and retrieve at least one particle." Adair discloses a flexible tube 24 having a stone removal basket 34 connected to one end. The stone removal basket 34 "includes a plurality of spaced outwardly bowed flexible members 36, connected at one end to the distal end of tube 24 and connected at the other end to a circular ring 38 which has a central opening 40, best seen in FIGS. 3 and 9," (col. 4, lines 8-13.) As is described and shown in FIGS. 3 and 9 of the Adair patent, each member 36 is a separate piece that is connected at each end to another part of the device. Thus, Adair discloses a basket 34 of multiple-piece construction. By definition, a multi-piece structure is not monolithic. This monolithic structure of the present invention is created by cutting away portions of a tube to form the slotted retrieval basket section. Adair does not teach or suggest a monolithic retrieval basket. The monolithic structure is more reliable than a multiple-piece construction, which would be subject to breakage at the connections. Moreover, the multiple-piece construction limits the size of the device due to the complexity of making the connections between the multiple pieces. In

addition, Adair is silent as to the material the basket 34 is made of, and thus does not teach or suggest a memory metal tube programmed for a memory effect or superelastic effect.

For this teaching, the Examiner cites Wilk. Wilk describes a tube used for draining an abscess, which has been provided with longitudinal slits to make the distal section expandable. The tube has a large diameter because an obturator has to fit inside the tube to hold the slotted section in its restrained, unexpanded shape upon insertion. This is done by exerting a longitudinal force on the tube, thus stretching the slotted section. A radial force is not applied to the tube. Upon release of the longitudinal force, the slotted section springs back and assumes a radially expanded configuration. The expanded slots are designed to anchor the tube to allow for drainage, not surrounding contact, capture and retrieve particles as with the device of the present invention.

The slotted distal end portion is described as being made of a flexible material with a spring bias, though Wilk does not specifically disclose what type of material that would be. One skilled in the art, however, may appreciate that the material would likely be a polymer. The spring bias will be caused by the elastic behavior of the preshaped expanded tip. When the obturator is pushed into the tube, it will cause a longitudinal stretching, as stated. It must then be locked in that position or it will spring back to its unstretched state. If the expanded section were made of a metal, the force needed to stretch the struts completely into a cylindrical shape, against their elastic tendency to expand, would be very high. Wilk simply does not describe the use of shape memory metal. A memory metal does not have a linear elastic behavior. In the superelastic state, the memory metal will undergo a stress induced transformation, wherein the original austenitic structure changes into a martensitic state, while high deformations can be

reached under an almost constant load. Release of this stress-induced martensite will cause the reverse transformation, back to the original austenitic start shape. This also happens under an almost constant stress over a wide strain. The loading and unloading values, causing this back and forth transformation, are called the loading/unloading plateau stress. These values are dependent on the alloy, heat treatment and thermo-mechanical history of the production. Wilk does not disclose the use of memory metal materials, and the spring bias that he describes is a simple linear elastic deformation such as that achievable in polymeric materials. Moreover, a polymeric material cannot be programmed for a memory effect or superelastic effect, as recited in claim 1. This feature of the claimed invention is achievable through use of memory metals.

Further, the shape memory basket is held under constraint in a surrounding delivery sheath, as we have described in the instant application. A strut that has the tendency to bend outside can be pushed into the stretched cylindrical state with a relatively small radial force. If this stretched state must be achieved by putting the same strut under axial tension, as in the case of the polymeric struts in Wilk, the needed force for a memory metal would have to be many times higher. Thus, neither Adair or Wilk teach or suggest a monolithic memory metal tube of single-piece construction programmed for an effect selected from the group of effects consisting of memory effect and superelasticity and having a slotted retrieval basket section capable of expansion and contraction to surrounding contact, capture and retrieve at least one particle. Therefore, there is no *prima facie* case of obviousness, and it is respectfully requested that the rejection of claim 1 be withdrawn. Moreover, even if the references are combined, the combination does not result in our claimed invention.

The Examiner states that "Adair is moot to the kind of material that the tube and the slots are made of" and that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Adair's slots and tube with Wilk's monolithic slits and tubular member." The Examiner further reasons that the selection of a memory metal in the art of endeavor has been rendered an obvious design choice" according to *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 U.S.P.Q. 297 (1945) and that one-piece constructions instead of the structure disclosed in the prior art would have been merely a matter of obvious engineering choice according to *In re Larson*, 340 F.2d 965, 968, 144 U.S.P.Q. 347 (CCPA 1965) (note the corrected case citation). With all due respect, the general holdings of these cases are not applicable to the facts of the present application. Unlike the facts of those cases, the monolithic structures of the present invention are not feasible with all materials, but rather, require shape memory and/or superelastic materials, such as nickel-titanium alloys, to achieve the single-piece construction having a basket programmed for a memory effect and capable of expansion and contraction. Cutting a monolithic structure from a conventional metal, such as stainless steel, would be very difficult with respect to shaping that structure into an expandable structure, like the retrieval basket. It is complicated to bend the struts to a basket shape and define the unstrained, expanded shape then. Very complicated tools would be needed and damage on the fine struts would easily occur.

Applicants recognized that by using a memory metal tube in the present invention, the production of a smooth basket is very easy and miniaturization is not an obstacle. Memory metal may be easily shape set by holding it in a restraining means and then applying simple heat treatment for a few minutes. For a basket, this can be done by just pushing or pulling the distal

and proximal ends of the basket section so far together that the struts automatically bend outward. Simple wire may be used for that purpose. The benefits of shape memory and/or superelastic materials were recognized by the Applicants and applied to retrieval baskets thereby enabling the formation of a monolithic retrieval basket. The selection of shape memory and/or superelastic materials is not a mere design choice. Applicant refers the Examiner to *United States v. Adams*, 383 U.S. 39, 148 U.S.P.Q. 479, 483 (1966), in which the Supreme Court explained the *Sinclair* case, relied upon by the Examiner, as follows:

There the patentee had developed a rapidly drying printing ink. All that was needed to produce such an ink was a solvent which evaporated quickly upon heating. Knowing that the boiling point of a solvent is an indication of its rate of evaporation, the patentee merely made selections from a list of solvents and their boiling points. This was no more than 'selecting the last piece to put in the last opening of a jigsaw puzzle.' . . . The solvent in *Sinclair & Carroll* had no functional relation to the printing ink involved. It served only as an inert carrier. The choice of solvent was dictated by known, required properties.

The Examiner has offered no evidence that memory metals were known in the art of retrieval baskets and like devices at the time of applicants' invention, or that memory metals function in the same manner in this application as other known materials. In fact, other materials known for use in retrieval baskets are not programmable for expansion and contraction as is a memory metal, such that the retrieval baskets of the prior art do not function in the same manner as the retrieval baskets of the present invention. Monolithic metal slotted baskets were not part of the prior art because their construction was not recognized as being feasible, such that devices were limited to multiple-piece constructions. The choice of material was not dictated by known, required properties, but rather, an inventive aspect of the present invention is the recognition of the potential properties of this relatively new type of material as they can be applied to improve

the manufacture and operability of retrieval baskets. The citation of a reference disclosing a flexible material having a spring bias, i.e., a polymer, does not teach or suggest a memory metal. Applicants have provided abundant explanation for the proposition that this is not a case of mere design choice, but rather the selection of a material having properties different than known materials in the art so as to enable a construction not previously achievable in devices in the art. For this additional reason, Adair in combination with Wilk does not teach or suggest a memory metal tube of single-piece construction programmed for a memory effect and/or superelasticity, such that there is no *prima facie* case of obviousness for claim 1. Applicants therefore respectfully request that the rejection of claim 1 be withdrawn.

Applicant further notes that there are numerous patents (see, e.g., U.S. Patent Nos. 6,159,220; 6,264,664; 6,350,266) that have issued on applications filed after filing of the instant application that are directed to retrieval baskets and like devices that have more complex, multi-piece constructions than the monolithic single-piece construction of the claimed invention, even with the use of nitinol materials. Thus, the industry continues to make complex devices, even while using shape memory metals, which is evidence that the monolithic, single-piece construction enabled by use of the memory metals is not obvious. The monolithic construction performs the same function, but is more reliable and easier to manufacture than these multi-piece constructions, and is therefore not obvious, otherwise the industry would be simplifying their constructions.

There is no teaching or suggestion in the art to substitute memory metals for the stainless steel materials previously used for retrieval baskets, and no recognition that doing so would allow for monolithic, single-piece retrieval baskets. In accordance with the Federal

Circuit decision of *In re Dembiczak*, 50 U.S.P.Q.2d 1614 (Fed. Cir. 1999), the analysis of patentability under § 103 requires the “critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field” to avoid the “tempting but forbidden zone of hindsight.” *Id. at 1616-1617*. As the Federal Circuit recognized, “[c]lose adherence to this methodology is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one ‘to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.’” *Id. at 1617* (citing *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983), *cert denied*, 469 U.S. 851 (1984)). As stated before, the presently claimed invention is deceptively simple, thereby potentially enticing the application of hindsight. Applicants respectfully assert that it has been established that the combination of references lacks the necessary suggestion, teaching or motivation and that the differences between the art of record and the claimed invention are not mere obvious design choices. “Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor’s disclosure as a blueprint for piecing together the prior art to defeat patentability—the essence of hindsight.” *Id.* Because the Examiner bears the burden of establishing a case of *prima facie* obviousness, and that burden has not been met, as set forth above, Applicants respectfully request that the rejection be withdrawn.

A Notice of Allowance as to both claims 1 and 7 is believed to be in order, and is respectfully requested. If the Examiner believes any detailed language of the claims requires further discussion, the Examiner is respectfully asked to telephone the undersigned attorney so

that the matter may be promptly resolved. The Examiner's prompt attention to this matter is appreciated.

Applicants are of the opinion that no additional fee is due as a result of this amendment. If any charges or credits are necessary to complete this communication, please apply them to deposit account no. 23-3000.

Respectfully submitted,

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